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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,590	09/30/1998	JEFFREY SCHLOM	2026-4230US1	8846

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	23

DATE MAILED: 01/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/155,590	Schlom et al.
Examiner	**Art Unit**
G. R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *4/11/01 and 10/19/01* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *10-25, 27, 32-34, 66-68, and 70* is/are pending in the application.

4a) Of the above, claim(s) *16-24* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *10-15, 25, 27, 32-34, 66-68, and 70* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Claims 10-15, 25, 27, 32-34, 66-68, and 70 are being acted upon.

2. The disclosure is objected to because of the following informalities: the instant application, filed 9/30/98, claims priority to U.S. Application No. 08/635,344, filed 4/19/96. The first line of the specification must be updated accordingly. Additionally, the first line of the specification must be amended to include the claim to priority of PCT/US97/06470, filed 4/17/97.

3. In view of Applicant's amendments and responses, filed 4/11/01 and 10/19/01, only the following rejections remain.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 34 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically: Claim 34 contains the trademark/trade name RIBI Detox™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a pharmaceutical composition and, accordingly, the identification/description is indefinite.

Applicant appears to have misunderstood the Examiner's suggestion of 6/27/01 regarding the amending of Claim 34. While the Examiner did indicate that RIBI Detox™ should be replaced with the formulation of RIBI Detox™, the Examiner did not mean that Applicant should literally use the words "RIBI Detox™

formulation." Said change would not remove the rejected trademark. The Examiner's intention was that Applicant claim an adjuvant consisting of the components of RIBI Detox™, i.e., mycobacterial cell wall extracts, monophosphoryl lipid A, etc.

6. Applicant is advised that the instant claims have not been granted the benefit of priority to parent application 08/635,344 as said application does not disclose the sequence comprising SEQ ID NO:14 of independent base Claim 10. The filing date of the instant application is considered to be the filing date of parent application PCT/US97/06470, 4/17/97.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10-15, 27, and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Van Elsas et al. (1995) or Gjertsen et al. (1996) in view of Ruppert et al. or U.S. Patent No. 5,861,372 (1999), for the reasons of record as set forth in Paper No. 16, mailed 10/11/01.

Applicant's arguments, filed 4/11/01, have been fully considered but they are not persuasive. Applicant argues that the '372 patent is not prior art. Applicant is incorrect, a U.S. Patent published less than 1 year prior to the filing date of an application is applied as prior art as of its filing date. The '372 patent has a filing date of 2/22/96 and is thus, proper prior art, see MPEP 706.02 (a) and (j). Applicant further argues that "Neither Van Elsas et al or Gjertsen et al teach or suggest mutant ras peptides having multiple substitutions at two or three positions. Both teach single substitutions at position 12 (Van Elsas et al) or at position 12 or position 13 (Gjertsen et al). Neither Van Elsas et al or Gjertsen et al teach or suggest substitutions at position 12, position 5 and/or position 7." However, Applicant is reminded that the references teach the elected species, YLVVVGADGV with a single substitution; said additional species are not under examination at this time. Applicant further argues that "the disclosure of Van Elsas et al would lead one skilled in the art away from reliance on Ruppert et al." It is the Examiner's position that the Ruppert et al.

reference teaches that a substitution of Y for K at the N-terminus of the claimed peptide would lead to increased HLA binding, thus proper motivation has been established.

Regarding Applicant's arguments that the Van Elsas et al. reference teaches that not all peptides could elicit a CD8+ immune response, said arguments are irrelevant. As the instant claims are drawn to a specific peptide (a peptide comprising YLVVVGADGV), motivation need only be established to produce the claimed peptide. The claimed peptide, absent the N-terminus Y, is taught by two different references (Van Elsas et al. or Gjertsen et al.). The Examiner has then provided two different reasons why one of skill in the art would have been motivated to ad an N-terminus Y to the peptide (Ruppert et al. or the '372 patent). Thus, proper motivation for producing the claimed invention has been established and the rejection is proper. Further, it is the Examiner's position that the properties of the claimed peptide, i.e., immune response-eliciting, comprise only further characterization of the invention and lend no patentable weight to the claims. As "predictability that the peptides will elicit a peptide-specific human CD8+ cytotoxic T lymphocyte immune response," comprises an irrelevant issue, the newly submitted Pogue et al. and Rivoltini et al. references lend no weight to Applicant's arguments.

9. Claim 25 and newly added Claims 66-67 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Van Elsas et al. (1995) or Gjertsen et al. (1996) in view of Ruppert et al. or U.S. Patent No. 5,861,372 (1999) as applied to claims 10-15, 27, and 32 above, and further in view of U.S. Patent No. 6,039,948 (2000), for the reasons of record as set forth in Paper No. 16, mailed 10/11/01.

Applicant's arguments, filed 4/11/01, have been fully considered but they are not persuasive. Applicant argues that the '948 patent can not be applied as prior art. Applicant is incorrect, see paragraph 8 above.

10. Claim 33 and newly added Claims 68 and 70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Van Elsas et al. (1995) or Gjertsen et al. (1996) in view of Ruppert et al. or U.S. Patent No. 5,861,372 (1999) as applied to claims 10-15, 27, and 32 above, and further in view of U.S. Patent No. 5,800,810 (1998), for the reasons of record as set forth in Paper No. 16, mailed 10/11/01.

Applicant's arguments, filed 4/11/01, have been fully considered but they are not persuasive. Applicant argues that the '810 patent can not be applied as prior art. Applicant is incorrect, see paragraph 8 above.

11. Claim 34 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Van Elsas et al. (1995) or Gjertsen et al. (1996) in view of Ruppert et al. or U.S. Patent No. 5,861,372 (1999) as applied to claims 10-15, 27, and 32-33 above, and further in view of U.S. Patent No. 6,001,349 (1999), for the reasons of record as set forth in Paper No. 16, mailed 10/11/01.

Applicant's arguments, filed 4/11/01, have been fully considered but they are not persuasive. Applicant argues that the '349 patent can not be applied as prior art. Applicant is incorrect, see paragraph 8 above.

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
January 9, 2002

Patrick J. Nolan, Ph.D.
Primary Examiner
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